

March 3, 1998

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Dockets Management Branch (HFA-305)  
12420 Parklawn Drive, Room 1-23  
Rockville, MD, 20857

Reference: ANPR refurbished devices, remarketers.

In house hospital maintenance groups and multi-hospital maintenance groups that are departments or owned companies of the parent hospital corporation should not be subject to the GMP guidelines.

The rationale for this opinion is the strong JACHO requirements already in existence for hospital accreditation. Hospital service and maintenance departments, and or those companies who provide this service, are already required to document their service support activities. Checks are in place to validate service quality and compliance for inspection frequencies, inspection quality levels, and staff education on equipment utilization. Additional regulations will only add financial burden to an already highly regulated industry.

Sincerely,



Stan Richards, CBET  
Director Biomedical Services

97N-0477

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ADDRESS SERVICE  
REQUESTED

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